

WHAT IS CLAIMED IS:

- 05 1. A monoclonal antibody characterized by its specificity for an epitope on HIV I gp41 formed by a first sequence of amino acids Ile-His-Ser-Leu-Ile-Glu-Glu-Ser-Gln-Asn-Gln-Gln-Glu-Lys-Asn-Glu-Gln-Glu-L
10 eu-Leu-Glu-Leu-Asp-Lys with at least one flanking amino acid sequence of at least 5 amino acids in length either 3' to the carboxy terminus or 5' to the amino terminus of said first sequence, said flanking sequence having an amino acid sequence substantially corresponding to that found on native HIV I gp41 adjacent said first sequence, said flanking sequence putting said first sequence into proper antigenic conformation.
2. An immortal, mammalian antibody-producing cell line that produces the monoclonal antibody of claim 1.
3. The cell line of claim 2, wherein said cell line is a hybridoma which comprises a cell hybrid of a mouse spleen cell
15 immunized with HIV I fused to myeloma cell line SP2/0.
4. A murine derived hybridoma cell line ATCC HB 9628.
5. A monoclonal antibody produced by the hybridoma cell line ATCC 9628 designated the 5-21-3 monoclonal antibody.
- 20 6. A method for detecting a marker indicative of exposure to HIV I in a sample comprising forming an antibody/antigen complex between the epitope on HIV I gp41 formed by a first sequence of amino acids
25 Ile-His-Ser-Leu-Ile-Glu-Glu-Ser-Gln-Asn-Gln-Gln-Glu-Lys-Asn-Glu-Gln-Glu-L eu-Leu-Glu-Leu-Asp-Lys with at least one flanking amino acid sequence of at least 5 amino acids in length either 3' to the carboxy terminus or 5' to the amino terminus of said first sequence, said flanking sequence having an amino acid sequence substantially corresponding to that found on native HIV I gp41 adjacent said first sequence and a
30 antibody specific for that epitope, and detecting the presence or amount of the antibody/antigen complex formed.

7. The method of claim 6 wherein the antibody/antigen complex is formed in an immunometric, competitive, sandwich, or agglutination assay format.

05 8. The method of claim 6 wherein the antibody is a monoclonal antibody.

9. The method of claim 8 wherein the monoclonal antibody is the monoclonal antibody of claims 1 or 5.

10. The method of claim 9 wherein the monoclonal antibody is labeled with a detectable label.

10 11. The method of claim 10 wherein said label comprises a radioisotope, enzyme, fluorescent compound, chemiluminescent compound or member of a specific binding pair.

15 12. An immunoassay for determining the presence or amount of antibody to HIV I gp41 in a test sample comprising incubating the test sample with a solid phase-bound binding material containing a target epitope having the immunological properties of the epitope on HIV I gp41 formed by a first sequence of amino acids
Ile-His-Ser-Leu-Ile-Glu-Glu-Ser-Gln-Asn-Gln-Gln-Glu-Lys-Asn-Glu-Gln-Glu-L
20 eu-Leu-Glu-Leu-Asp-Lys with at least one flanking amino acid sequence of at least 5 amino acids in length either 3' to the carboxy terminus or 5' to the amino terminus of said first sequence, said flanking sequence having an amino acid sequence substantially corresponding to that found on native HIV I gp41 adjacent said first sequence and with a probe antibody which specifically binds to the target epitope of the
25 binding material, and then determining the presence or amount of the probe antibody bound or unbound to the binding material as an indication of the presence or amount of antibody to HIV I gp41 in the test sample.

13. The immunoassay of claim 12, wherein said binding material comprises partially purified HIV I, native HIV I gp41, or full-length recombinant-derived gp41.

05 14. The immunoassay of claim 13, wherein said binding material is the recombinant product of the cloned BglII to KpnI restriction fragment of HIV I gp41 bound to said solid phase via human IgG positive for said gp41.

15. The immunoassay of claim 14, wherein the probe antibody is a monoclonal antibody of claims 1 or 5.

10 16. The immunoassay of claim 12 wherein the probe antibody is a monoclonal antibody.

17. The immunoassay of claim 16 wherein the monoclonal antibody is the monoclonal antibody of claims 1 or 5.

15 18. The immunoassay of claim 17 wherein the monoclonal antibody is labelled with a detectable label.

19. The immunoassay of claim 12, wherein the presence or amount of the probe antibody bound or unbound to the binding material is determined by incubating said probe antibody with a labeled , anti-species, second antibody.

20 20. The immunoassay of claims 18 or 19 wherein said label comprises a radioisotope, enzyme, fluorescent compound, chemiluminescent compound, or member of a specific binding pair.

21. A diagnostic kit for detection of exposure to HIV I comprising the monoclonal antibody of claims 1 or 5 as a reagent.